DABIGATRAN CONSISTENTLY INCREASES THE RISK OF ACUTE CORONARY DISEASE: A RANDOMIZED-CONTROLLED TRIALS META-ANALYSIS

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Background: Dabigatran is a direct thrombin inhibitor recently approved as an alternative to warfarin. The approval, however, carried a recommendation to describe in the label a possible increase in the incidence of myocardial infarction. We hypothesized that by pooling the literature we could confirm or reject this concern.

Methods: All randomized controlled trials utilizing dabigatran were sought in PubMed and the Cochrane databases during November 2011. Trials that compared the use of dabigatran and warfarin were analyzed for acute coronary syndrome (ACS).

Results: There were 50 randomized controlled trials, of which only 4 compared dabigatran to warfarin, reported ACS, and were unique studies. Two trials tested the use of dabigatran for atrial fibrillation, and two for venous thromboembolism. Multiple dosages were used in 2 of the trials making available a total of 7 groups. In all groups, despite the dosage, ACS was increased in the dabigatran groups with a relative risk increase of 46% (p=0.0007), when considering all dabigatran dosages. A similar increase in risk was found across all studied dosages of dabigatran (Figure 1).

Conclusions: The current available data is consistent with a hypothesis that dabigatran is associated with an increased incidence of ACS when compared with warfarin, this should be taken in consideration when selecting anti-coagulant agent as multiple agents are now available and it can influence outcomes. Further studies are necessary to clarify this effect but.